

APR 14 2009

**510(k) SUMMARY**  
**for**  
**Adaptable Composite Resin Restorative Material**

1. Submitter Information:

DENTSPLY International  
Susquehanna Commerce Center  
221 West Philadelphia Street  
York, PA 17405

Contact Person: Helen Lewis  
Telephone Number: 717-849-4229  
Fax Number: 717-849-4343

Date Prepared: December 19, 2008

2. Device Name:

- Proprietary Name: Adaptable Composite Resin Restorative Material
- Classification Name: Tooth Shade Resin Material
- CFR Number: 872.3690
- Device Class: II
- Product Code: EBF

3. Predicate Device:

| Company                   | Device                      | 510(k) Number | Date Cleared |
|---------------------------|-----------------------------|---------------|--------------|
| DENTSPLY<br>International | Quixx Posterior Restorative | K040144       | 04/01/2004   |
|                           | Flowable Composite          | K981965       | 07/10/1998   |

4. Description of Device:

The Adaptable Composite Resin Restorative Material is a one-component, fluoride-containing, visible light cured, radiopaque resin composite restorative material.

5. Indications for Use:

Adaptable Composite Resin Restorative Material is indicated for the following procedures:

1. Indications with tooth/restorative interface

- Class III and V restorations
- Conservative Class I restorations
- Small Class IV repairs
- Tunnel Preparations
- Filling of defects and undercuts in crown, inlay and onlay preparations
- Blockouts
- As a liner under direct restorative materials and under inlay restorations - Class II box liner

- As a base or liner for cavity Class I and II restorations
  - Repair of small enamel defects
  - Covering incisal edge stains
  - Pit and fissure sealant
2. Indications including tooth/indirect restorative materials
- Cementing porcelain veneers, crowns, inlay and onlays
  - Intraoral porcelain repair
3. Amalgam margin repair
4. Provisional or Indirect Laboratory Indications:
- Improving margins of acrylic temporaries
  - Provisional occlusal changes
  - Refacing acrylic temporaries
  - Margin correction/adjustment of composite crowns for indirect laboratory use
6. Description of Safety and Substantial Equivalence:
- Technological Characteristics.  
The technological characteristics (i.e., chemical composition and device function) of Adaptable Composite Resin Restorative Material are similar to that of the predicate devices. One difference is that the Adaptable Composite Resin Restorative Material has significant low shrinkage stress.
- Non-Clinical Performance Data.  
Standard biocompatibility tests were performed on the Adaptive Composite Resin Restorative Material. All tests were performed in accordance with ISO 10993-1 (*Biological Evaluation for Medical Device-Part 1: Evaluation and Testing*) and ISO 7405 (*Dentistry-preclinical evaluation of biocompatibility of medical devices used on dentistry- Test methods for dental materials*). The studies indicated that the Adaptive Composite Resin Restorative Material is biocompatible and safe for its intended use.
- In-vitro bench tests were performed on the Adaptive Composite Resin Restorative Material. The results indicated that the Adaptive Composite Resin Restorative Material meets or exceeds the requirements of ISO 4049 (*Dentistry-Polymer-based filing, restorative and luting materials*) and safe for its intended use.
- Conclusion as to Substantial Equivalence  
We believe that the prior use of the components of Adaptable Composite Resin Restorative Material in legally marketed devices, the performance data provided, and the biocompatibility data provided support the safety and effectiveness of Adaptable Composite Resin Restorative Material for the indicated uses.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 14 2009

Ms. Helen Lewis  
Director, Corporate  
DENTSPLY International  
221 West Philadelphia Street  
York, Pennsylvania 17405-0872

Re: K083841

Trade/Device Name: Adaptable Composite Resin Restorative Material  
Regulation Number: 21 CFR 872.3690  
Regulatory Class: II.  
Product Code: EBF  
Dated: April 3, 2009  
Received: April 8, 2009

Dear Ms. Helen Lewis:

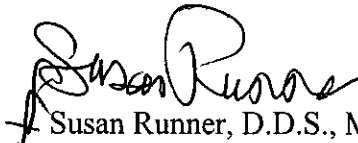
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0100. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan Runner", is written over the typed name.

Susan Runner, D.D.S., M.A.  
Acting Director

Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K083841

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- Repair of small enamel defects
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- Pit and fissure Sealant

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- Cementing porcelain veneers, crowns, inlays/onlays
- Intraoral porcelain repair

3. Amalgam margin repair

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Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

[Signature]  
(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices